K050716

APR 2 1 2005

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON, AND DATE SUMMARY PREPARED

APPLICANT

iScience Surgical Corporation
3696A Haven Avenue
Redwood City, CA 94063
Ron Yamamoto
Phone (650) 421-2700
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Contact Person:

CONTACT PERSON:

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2 Delphinus
Irvine, CA 92612
Phone (949) 854-6314
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2. NAME OF DEVICE, INCLUDING TRADE NAME AND CLASSIFICATION NAME:

TRADE/PROPRIETARY NAME: iScience Surgical Ophthalmic ViscoInjector, abbreviated as VI

COMMON NAME: ViscoInjector

CLASSIFICATION NAME: Pump, Infusion, Ophthalmic

3. DEVICE DESCRIPTION

The iScience Surgical Ophthalmic ViscoInjector consists of a holder for a viscoelastic cartridge which incorporates a manually operated screw driven plunger. For use, a cartridge of viscoelastic solution is placed into the body of the Ophthalmic ViscoInjector. A needle inside the Ophthalmic ViscoInjector pierces the septum of the viscoelastic cartridge as it is seated within the body cavity. The cap from the Ophthalmic Viscoinjector is connected to the body to secure the cartridge of viscoelastic solution inside the ViscoInjector. The thumbwheel is rotated clockwise thereby advancing the screw driven plunger to deliver viscoelastic solution.

The end of the screw has a bushing that contacts the stopper in the viscoelastic cartridge. As the screw is advanced at a controlled rate the stopper displaces fluid out through the needle that has pierced the septum.

The opposite, blunt end of the needle is embedded in a male Luer lock connector. This connector may be mated to a female Luer connector and the viscoelastic solution delivered. Markings on the thumbwheel, cap, and body of the ViscoInjector are provided to assist in determining the number of complete or partial thumbwheel rotations and thus relate to the amount of fluid delivered.

4. INDICATION FOR USE

The iScience Surgical Ophthalmic Viscoinjector is a manually operated device for precision delivery of small amounts of viscous fluid such as a sterile viscoelastic solution pre-packaged in a cartridge, for example Healon, HealonGV and Healon5 manufactured by Advanced Medical Optics Inc., and Ocucoat manufactured by Bausch and Lomb.

5. PREDICATE DEVICES

The iScience Surgical Ophthalmic ViscoInjector is substantially equivalent to the following predicate devices:

Company:	Viscous Fluid Injector System Module (CX5700)
Device:	Bausch & Lomb Inc.
510(k):	K993039
Company:	Grieshaber & Co.
Device:	Grieshaber Viscoelastic Injection System
510(k):	K890783
Company:	D.O.R.C VFI VFE System
Device:	Dutch Ophthalmic USA, INC.
510(k):	K954842
Company:	Viscous Fluid System
Device:	Escalon Trek Medical
510(k):	K963434

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The intended use and technological features of the iScience Surgical Ophthalmic Viscoinjector do not differ from the legally marketed predicate devices. Both the Ophthalmic Viscoinjector and the predicate device(s) utilize similar materials and methods of operation.

7. SUMMARY OF PERFORMANCE DATA

The iScience Surgical Ophthalmic Viscoinjector has been shown to conform to the following standards, practices, and guidances:

STERILIZATION

- ANSI/AAMI/ISO 11137-1994, *Sterilization of Health Care Products – Requirements for Validation and Routine Control – Radiation Sterilization* .

SHELF-LIFE AND PACKAGING INTEGRITY

- ANSI/AAMI/ISO 11607-1997, *Packaging for Terminally Sterilized Medical Devices.*
- AAMI TIR, Guidance for ANSI/AAMI/ISO 11607-1997, *Packaging for Terminally Sterilized Medical Devices, 1997.*

PERFORMANCE

In the absence of performance standards for viscoelastic injectors or pumps, ISO 7886-1 "Sterile hypodermic syringes for single use- Part 1: Syringes for manual use" was used for general guidance in design evaluation and performance testing of the iScience Surgical Ophthalmic Viscoinjector. Performance testing was designed to evaluate strength of the device joints, static pressure failure, and delivery of fluid such as a viscoelastic solution. Determination of acceptance criteria was based on general experience with syringe-type devices, intrinsic strength of the Viscoinjector materials, and the load to which the iScience Surgical Ophthalmic Viscoinjector would be subjected during intended use.

8. CONCLUSION

Since the iScience Surgical Ophthalmic Viscoinjector meets the requirements of the stated standards and embodies technological characteristics similar to the predicate devices, the device has been shown to be substantially equivalent to the predicate devices, is as safe and effective and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 1 2005

iScience Surgical Corporation
c/o Judy Gordon, DVM
ClinReg Consulting Services, Inc.
2 Delphinus
Irvine, CA 92612

Re: K050716
Trade/Device Name: iScience Ophthalmic Viscoelastic Injector
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: MRH
Dated: March 16, 2005
Received: March 21, 2005

Dear Dr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K050716

Device Name: **iScience Surgical Ophthalmic ViscoInjector**

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-The-Counter Use** ____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises